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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,293	12/31/2003	Sangeeta N. Bhatia	1034123-000095	9194
41790 7590 07/31/2007 BUCHANAN, INGERSOLL & ROONEY LLP P.O. BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER KUHN, ALLAN R	
			ART UNIT 1732	PAPER NUMBER
			MAIL DATE 07/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,293	Applicant(s) BHATIA ET AL.	
	Examiner Allan Kuhns	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31 and 34-64 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 and 54-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,34-38,45-53 and 60-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>051004&092904</u> . | 6) <input type="checkbox"/> Other: _____ |

1.Applicants' election of the species directed to the biopolymer on April 20, 2007 is noted by the examiner. Consequently, claims 39-44 and 54-59, directed to the "coating" embodiment, are hereby withdrawn from consideration.

2.The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4.Claims 30, 34-38, 45, 46, 49 and 64 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ma (6,872,387). Ma discloses the basic claimed polymer scaffold. Note column 2, lines 18-24. Alternatively, it would have been obvious to one of ordinary skill in the art to form a polymer scaffold by molding in order to form the scaffold into a desired shape. Note MPEP 2113 for treatment of product-by-process claims. It is submitted that a polymer will inherently adopt a microstructure complementary to that of a mold surface such that it would have been obvious to one of ordinary skill in the art to produce a microfabricated scaffold.

Ma teaches the forming of a scaffold from a biopolymer, as in claim 35, which may be a hydrogel (column 4, lines 26-35), as in claim 37, and polyvinyl alcohol, as in claim 38. Forming a scaffold from PLA, PLLA or PLGA, as in claim 36, is well known and would have been obvious to one of ordinary skill in the art in order to make use of the biodegradable properties of the polymer. Claim 34 is directed to the material of the mold itself, rather than the scaffold. Claims 45 and 46 are directed to a method of making a scaffold, rather than the structure of the scaffold. Ma teaches the inclusion of cells with the scaffold, as in claims 49 and 64.

5. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma as applied to claims 30, 34-38, 45, 46, 49 and 64 above, and further in view of Chu et al. (6,790,455). Chu et al. disclose the aspect of forming multiple layer scaffold-like structures at column 14, line 23. It would have been obvious to one of ordinary skill in the art to assemble such layers, as in claim 47, in order to form more complex structures, as taught by Chu et al. at column 15, lines 32-48. It is the structure itself, rather than a method of forming the structure, as in claim 48, which is being evaluated.

6. Claims 31, 50-53 and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (6,790,455). Chu et al. disclose or suggest the basic claimed membrane structure, for example at column 15, lines 32-48. Since Chu et al. discuss the formation of scaffolds having a complex form at column 15, line 34, it would have been obvious to one of ordinary skill in the art to provide a surface of varied or varying topology in order the scaffold with a complex shape.

It is submitted that the membrane of Chu et al. is inherently porous or mesh-like, as in claims 60 and 61. Chu et al. teach or suggest the attachment of cells, as in claim 63, at column 15, line 32, for example, and the use of a plurality of membranes, as in claim 62, at column 14, lines 19-26. Chu et al. teach the use of a biopolymer, as in claim 50, which may be PLA (column 15, line 36), as in claim 51, as well as a hydrogel (column 9, line 1), as in claim 52. Scaffolds from hydrogels selected from the group of claim 53 are well known and their selection would have been obvious to one of ordinary skill in the art in order to incorporate particular physical properties into the hydrogel (note Ma at column 4, lines 26-35).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allan Kuhns whose telephone number is (571) 272-1202. The examiner can normally be reached on Monday to Thursday from 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allen R. Kuhns

ALLAN R. KUHNS
PRIMARY EXAMINER AU 1732